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| 10/533,534 | 06/22/2005 | Jun Mori | 123680 | 1629 |

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| EXAMINER | |
|---|---|
| YOUNG, MICAH PAUL | |
| ART UNIT | PAPER NUMBER |
| 1618 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/533,534 | MORI ET AL. | |
| | Examiner | Art Unit | |
| | MICAH-PAUL YOUNG | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *7/7/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-6 and 8-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

### *Claim Objections*

Claims 1,6, 11 and 12 are objected to because of the following informalities: Claims 1 and 16 misspells the term Eudragit as *Eudragid*. Appropriate correction is required. Claims 11 and 12 misspells the term retinal as *rental*. Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 6 contain the trademark/trade name Eudragit (misspelled as Eudragid). Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the

trademark/trade name is used to identify/describe polyacrylic copolymers and, accordingly, the identification/description is indefinite.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-6, and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Uchiumi et al (JP 10-279480 hereafter '480) in view of Koide et al (JP 10-265373 hereafter '373) and Mori et al (EP 1 174 132 hereafter '132).

The '480 patent discloses a topical drug formulation comprising 3-methyl-1-phenyl-2-pyrazolin-5-one in combination with well known excipients (abstract). The formulation comprises water soluble polymers such as polyvinylpyrrolidone, alcohols such as ethanol, and a mass of water [0013-0014]. The reference is silent to the concentrations of the carrier formulation however the active compound is present up to 50% of the composition (abstract).

Topical carrier formulation are fairly well known in the art whether rubber or aqueous based, the components are well know and common in the art. This can be seen in the '373 and '132 patent. The prior art provides a wide range of active agents combined into topical formulations that can be either aqueous based or rubber based.

The '373 patent discloses a tacky adhesive composition comprising a drug, water-soluble polymer, cross-linking agent a polyhydric alcohol and water (abstract). The water soluble polymers include polymers such as polyacrylates, Carbopol, cellulose polymers, xanthan, alginates, and polyacrylics [0012-0020], and these polymers make up 1-15% [0014]. The formulation comprises crosslinking agents that make up from 0.1-10% of the formulation and include glycine [0017-0019]. The formulation comprises polyhydric alcohols such as ethylene glycol and propylene glycol that make up from 15-50% of the formulation [0020-0021]. The formulation further comprises tackifiers such as cellulosic resins, where the compounds are present in the formulation up to 15% [0020]. The water content of the formulation ranges from 40-70% [0038]. The drugs range from 0.001-10% of the drug formulation [0031] and can range from anti-inflammatory agents to muscle relaxants and vitamins [0030-0031]. These compounds are useful for treating diabetes, cancer, pain or as a sun-block [0029]. The tacky formulation is applied to a film or substrate and applied to the skin [0022]. The tacky topical formulation, while disclosing a wide range of active agents is silent to the specific active agent of the instant claims.

The '132 patent discloses a topical dosage form comprising from 0.01-305 of an active agents present in either an aqueous base or rubber based carrier formulation (abstract, [0019]). The carrier formulation comprises from 10-50% of a rubber base such as styrene butadiene

copolymers [0028], plasticizers such as animal or vegetable oils present in a concentration from 0.5-20% [0025], and tackifiers such as propylene glycol present in an amount from 20-70% [0023]. The formulation can also be an aqueous based transdermal comprising water-soluble polymers such as polyacrylics acid and polyacrylamides in an amount from 3-70% [0027], crosslinking agents present in an amount from 0.1-20% [0022], and a polyhydric alcohol from 20-70% [0023] and 10-70% by weight of water [0040]. It would have been obvious to include the compound of the '480 patent into either carrier formulation since many of the same excipients are present.

Regarding the specific ranges of the instant claims it is the position of the Examiner that such limitations are obviated by the proposed combination. The general conditions of the claims have been met with each result effective parameter being met by the prior art. A transdermal formulation comprising an aqueous base comprising a water soluble polymer, a polyhydric alcohol, a crosslinking agents and a mass of water is disclose aqueous the prior art. The carrier formulation of the '373 patent is similar enough to the instant claims that any modifications would be obvious to one of ordinary skill in the art, as a result of routine experimentation. The formulation would comprise the same components and be used for the same purposes including arteriosclerosis. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time

of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

It would have been obvious to combine the compound of the '480 patent into the topical preparation of the '373 patent or the '132 patent in order to improve the transdermal delivery of the '480 compound. The carrier formulations would have provided a transdermal with reduced skin irritation and improved drug permeability. One of ordinary skill in the art would have been motivate to make this combination with an expected result of stable percutaneous formulation useful in treating skin tissue disturbances.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-6 and 8-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/579,055. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to percutaneous formulations comprising either an aqueous base or rubber base and 0.1-30 percent by mass of 3-methyl-1-phenyl-2-pyrazolin-5-one. The formulations comprise an aqueous or rubber base, a water soluble polymer, a crosslinking agent, polyhydric alcohol and water. The instant claims recite specific polymers as defined by the instant specification as meeting each of these compositional components. The instant claims recite specific water soluble polymers such as polyacrylamides, polyethylene imines, carboxyvinyl polymers, starch acrylate, and starch. These polymers are recited in the Specification as useable water soluble polymers. The copending claims, though broader would be encompassed by the instant claims. Also, the copending claims recite a method of making the same percutaneous formulation. The only active step in the method is combining the ingredients together. The result of this method is the same percutaneous drug formulation comprising the same drug, water-soluble polymers, tackifiers, cross-linkers and polyhydric alcohol as the instant claims. It would have been obvious to use the method of making a percutaneous formulation as recited in the copending '055 patent in order to make the composition of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

Applicant's arguments, see Remarks, filed 7/7/09, with respect to the rejection(s) of claim(s) 1,3-6 and 8-12 under USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Uchiumi et al (JP 10-279480 hereafter '480) in view of Koide et al (JP 10-265373 hereafter '373) and Mori et al (EP 1 174 132 hereafter '132).

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618